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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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WASHINGTON, DC 200373202

EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/373,585

Applicant(s)

OGURA, NOBUHIKO

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7 and 14-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on August 29, 2003 has been entered. The claims pending in this application are claims 6, 7, and 14-25. Rejection and/or objection not reiterated from the previous office action have been withdrawn in view of the response filed on August 29, 2003. The following rejections are based on amendment filed on February 5, 2001.

Claim Objections

2. Claims 7 and 22-25 are objected to because of the following informality: "an apparatus" should be "the apparatus".
3. Claims 15, 16, 18, and 19 are objected to because of the following informality: "a system" should be "the system".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 17 is rejected as vague and indefinite because it is unclear whether "the respective fluorescence dyes" are identical to different fluorescent dyes or not. Please clarify.

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7. Claim 17 is rejected as vague and indefinite because it is unclear whether “the respective sample organisms” are identical to at least a pair of different sample organisms or not. Please clarify.

8. Claim 17 is rejected as vague and indefinite in view of the phrase “determines the difference between the substances derived from the respective sample organisms on the basis of the specific binding agents with which the substances derived from the respective sample organisms are hybridized with each other” because it is unclear what this phrase means. Please clarify.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 14-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Stern *et al.*, (US Patent 5,631,734, filed on February 10, 1994).

Stern *et al.*, teach that method and apparatus for detection of fluorescently labeled Materials.

Regarding claims 14, 16, 17, 19, and 20, Stern *et al.*, teach an apparatus for detecting fluorescently marked regions on a first surface of a substrate, said apparatus comprising: (1) an excitation light source; (2) an optical train for directing an excitation light from said excitation

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light source at said substrate, and separating reflected excitation light from said first surface from fluoresced light from said first surface, said optical train comprising a spatial filter having a first lens and a second lens and a confocal pinhole located between said first lens and said second lens, a beam splitter cube, and a dichroic mirror for passing light having a wavelength of about said fluoresced light and reflecting light having a wavelength of about said excitation light, an optical lens and a microscope objective for directing said light at said substrate; (3) a focusing system for determining a focal plane of said excitation light passing through said optical train, said focusing means providing data for locating said first surface at said focal plane; (4) a detector for detecting said fluoresced light from said fluorescently marked regions in response to said light; (5) an x-y-z translation system for translating said substrate from a first position to a second position; (6) a flow cell mounted on said translation system, said flow cell comprising a mounting surface with a cavity therein, said mounting surface including a means for mounting said substrate thereon, and maintaining a sealed relationship with said substrate, whereby said first surface of said substrate is in fluid communication with said cavity, said cavity having an inlet and an outlet, and said inlet being connected to a pump for transferring materials into said cavity through said inlet and out of said cavity through said outlet; and (7) a storage system for storing a set of values representing an intensity of said fluoresced light as a function of the location on said substrate fluorescing said fluoresced light (see column 17, claim 1). Since Stern *et al.*, teach that the light source 100 generates a beam of light to excite the fluorescein labeled targets in the flow cell (see column 5, fourth paragraph) and teach a detector for detecting said fluoresced light from said fluorescently marked regions in response to said light (see above), Stern *et al.*, disclose an exciting light source and a photodetector as recited in claims 14 and 17.

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Since Stern *et al.*, teach an x-y-z translation system for translating said substrate from a first position to a second position, Stern *et al.*, disclose a conveyor as recited in claim 14. Since the detector comprises a photomultiplier tube that is coupled to a means for collecting pulses generated by said photomultiplier tube in response to said fluoresced light and said means for collecting pulses being connected to a programmable computer for storing and analyzing said pulses (see columns 17 and 18, claims 5 and 7), Stern *et al.*, disclose an analysis means recited in claim 14. Stern *et al.*, teach that , after data are collected from a region of the substrate, substrate is moved so that light can be directed at a different region on the substrate. The process is repeated until all regions on the substrate have been scanned (see column 7, last paragraph), Stern *et al.*, must disclose a scanning system as recited in claims 16 and 19. Although Stern *et al.*, do not specially indicate that their apparatus can perform the functions of the system recited in claims 14, 16, 17, 19, and 20, note that, while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not

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differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Exparte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) (see MPEP 2114).

Regarding claims 15 and 18, since claims 14 and 17 are directed to a system for reading a test piece comprising a strip-like substrate bearing thereon numbers of known specific binding agents which are different from each other and are arranged in a line at predetermined intervals in the longitudinal direction of the strip-like substrate, the test piece recited in preambles of claims 15 and 18 are not a part of a system as recited in claim 14. Therefore, claims 15 and 18 are anticipated by Stern *et al.*.

Therefore, Stern *et al.*, teach all limitations recited in claims 14-20.

Response to Arguments

In page 7, first paragraph bridging to page 12, first paragraph of applicant's remarks, applicant argues: (1) “there is no evidence that the probes are arranged in a line at predetermined intervals in the longitudinal direction of the strip-like substrate. Stern merely indicates that the substrate 230 comprises a number of presynthesized probes on its surface (column 3, lines 43-45), but it is unclear as to whether the probes are arranged in a line at predetermined intervals.”; (2) “[I]n Stern, the XYZ translation table clearly moves in three different directions and not along a single axis. In addition, Stern requires that three axes of movement be employed in order to scan a substrate, whereas the present invention only requires a single axis of movement to scan a substrate (claims 14 and 20).”; (3) “[T]he present invention describes a conveyor moving along a single axis. The conveyor of Stern, moves along multiple axes. There is no indication in Stern that one of ordinary skill in the art would be motivated to convey a substrate in a single

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axis. In particular, conveying the substrate of Stem along a single axis would lead to an incomplete scanning of the substrate as indicated above.”; (4) “the Examiner has not shown that the system can perform the functions of analysis described in claim 17.”; and (5) “the Examiner has not established that the binding agents are cDNA as described in claims 15 and 18.”.

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, applicant’s arguments are not directed to structures of the apparatus taught by Stern *et al.*, but appears to argue functions of apparatus taught by Stern *et al.*, it is known that, while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board’s finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) (see MPEP 2114). Therefore, since Stern *et al.*, teach all structural limitations recited in claims 14-20 (see above rejection), claims 14-20 are anticipated by Stern *et al.*. Second, since claims 14 and

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17 are directed to a system for reading a test piece comprising a strip-like substrate bearing thereon numbers of known specific binding agents which are different from each other and are arranged in a line at predetermined intervals in the longitudinal direction of the strip-like substrate, the test piece recited in preambles of claims 15 and 18 are not a part of a system as recited in claim 14. Therefore, claims 15 and 18 are anticipated by Stern *et al.*

11. Claims 6, 7, 21, 22, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Stimpson (US Patent No. 6,037,186, filed on July 16, 1997) as evidence by US patent No. 4,877,745 (Hayes *et al.*, published on October 31, 1989).

Stimpson teaches parallel production of high density arrays.

Regarding claims 6, 22, and 25, since Stimpson teaches that an automated device to apply the multitude of reagents to a 21.5 foot sheet is assembled from an X-Y-Z table (e.g. Asymtek) fitted with a reagent dispenser, a step motor controlled take up spool and an adjustable drag pay-out spool (see column 8, third paragraph and Figure 2C), Stimpson discloses a conveyor recited in claim 6. Stimpson teaches that, using reagent jet printing, lines of different DNA samples such as cDNA libraries are applied to the sheet in lines or otherwise a pin applicator so that multiple dots from the pin overlap to form a line wherein the different reagent lines on the sheet are formed as close together as possible and with minimum line width allowed by the printing method so that array density is maximized. For example, reagent jet printing is described in U.S. Pat. No. 4,877,745 and print lines with a width on the order of 0.001 inch (see column 7, lines 25-55). Since a plurality of jetting heads in the reagent jet printing taught by in U.S. Pat. No. 4,877,745 is arranged at predetermined or fixed interval (see Figure 1), Stimpson as evidence by U.S. Pat. No. 4,877,745 (Hayes *et al.*,) teaches a plurality of applicators as recited in claims 6

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and 25. Since the sheet with different DNA sample is cut with a razor blade, Stimpson discloses a cutting means as recited in claim 6. Although Stimpson as evidence by U.S. Pat. No. 4,877,745 (Hayes *et al.*,) does not specially indicate that his apparatus can perform the functions of the apparatus recited in claims 6 and 22, note that, while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) (see MPEP 2114).

Regarding claims 7 and 21, since claim 6 is directed to an apparatus for manufacturing a test piece for use in biological analysis of a sample organism comprising a strip-like substrate bearing thereon numbers of known specific binding agents which are different from each other and are arranged in a line at predetermined intervals in the longitudinal direction of the strip-like

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substrate, the test piece recited in claims 7 and 21 is not a part of a system as recited in claim 6.

Therefore, claims 7 and 21 are anticipated by Stimpson as evidence by U.S. Pat. No. 4,877,745.

Therefore, Stimpson as evidence by U.S. Pat. No. 4,877,745 teaches all limitations recited in claims 6, 7, 21, 22, and 25.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stimpson (July 16, 1997) as evidence by U.S. Pat. No. 4,877,745 as applied to claims 6, 7, 21, 22, and 25 above, and further in view of Shuminov (US Patent No. 5,808,554, 102(e) date: July 2, 1997).

The teachings of Stimpson have been summarized previously, *supra*.

Stimpson does not disclose a conveyor belt as recited in claim 23 and a guide rail as recited in claim 24.

Shuminov teaches moisture detecting liner for a diaper and a process for manufacture thereof a production line for manufacturing the diaper. Figure 4a shows schematically a production line for manufacturing the diaper. The production line comprises a drum 48 constituting a first roll, which feeds a tissue-type material 49 under a guide rail 50 so that, as the absorbent layer 45 passes underneath the guide rail 50, the tissue-type layer 49 is compacted on

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to the absorbent layer 45 thus forming a composite layer which is cut by a cutter 51 so that the tissue-type layer 49 extends along the complete length of the absorbent layer 45 and across the narrow section of its I-shaped contour. The composite layer passes along the conveyor belt 46, downstream of which are disposed, on opposite sides of the conveyor belt 46, a pair of drums 52 and 53 constituting, respectively, second and third rolls, which feed corresponding innermost and outermost layer material 54 and 55 so as to cover opposite surfaces of the composite layer comprising the absorbent layer 45 and the tissue-type layer 49. The resulting assembly is cut by a cutter 56 so as to produce the finished diaper (see Figure 4a and column 6, lines 5-21). The phrase "wherein said cutting edge moves along said guide rail" is a function of the cutting edge and is not a structural limitation recited in claim 24.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made added a conveyor belt as recited in claim 23 and a guide rail as recited in claim 24 into the apparatus recited in claim 6 in view of the patents of Stimpson and Shuminov. One having ordinary skill in the art would have been motivated to do so because a guide rail on the apparatus recited in claim 6 would compact a sheet (ie., a composition layer) that passes underneath of the guide rail and a conveyor belt on the apparatus recited in claim 6 would deliver a sheet (ie., a composition layer) to a cutter so that the sheet is cut to a designed size (ie., finished diaper) (see Shuminov, column 6, lines 5-21). One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to add a conveyor belt as recited in claim 23 and a guide rail as recited in claim 24 into the apparatus recited in claim 6.

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Response to Arguments

14. Applicant's arguments with respect to claims 6, 7, and 21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. No claim is allowed.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is 571-272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.



Frank Lu
PSA
January 16, 2004